

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB04/02720

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>1-41</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-41</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-41</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 1-41 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus or method of analyzing amniotic fluid comprising the steps or structures for providing a device for measuring one or more selected biological markers in amniotic fluid; arranging the device with respect to an amniotic sac to measure amniotic fluid in situ without insertion of any instrument into the amniotic sac; using the device to acquire measurement data; and processing the measurement data to obtain a value for the one or more selected biological markers in the amniotic fluid.

Claims 1-41 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.